



State of Connecticut

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August 21, 2005

Robert Rappaport, MD
Division of Anesthesia, Analgesia and Rheumatology
5600 Fisher's Lane
Rockville, MD 20857

Re: Petition 2005P-0267 (American College of Gastroenterology)

Dear Dr. Rappaport,

As Deputy Minority Leader of the Senate and member of the Connecticut General Assembly, I am writing to you regarding an issue which has the potential to adversely affect the quality of patient care in Connecticut. On June 28, 2005, a petition was filed by the American College of Gastroenterology (ACG) to modify the warning label of the sedative drug, Propofol. The ACG is requesting that the section pertaining to administration by individuals trained in general anesthesia be removed from the drug's warning label. This label change poses an imminent and severe threat to quality healthcare and patient safety.

Propofol is a potent and rapidly acting anesthetic medication that is commonly used to induce general anesthesia or heavily sedate patients. Because of its fast onset and the ability for patients to recover from it much more quickly than other anesthetics, it has become the anesthesia drug of choice for many office-based procedures like colonoscopies. According to Anesthesia experts, Propofol can also cause respiratory and cardiovascular depression, and the line between heavy sedation and general anesthesia is frequently breached. Due to the potential for rapid, profound changes in sedative/anesthetic depth and the lack of antagonist medications, the American Society of Anesthesiologists recommends that agents such as Propofol be administered by individuals who have undergone in-depth and formal comprehensive training in airway management and resuscitation.

This is also why the FDA calls for the person administering it to be trained in anesthesia. Clearly, any change in this warning label presents a significant and needless risk to patient care. This is particularly true in office-based and surgery center-based facilities where the paucity of emergency and critical care resources creates a looming danger. The thought of a gastroenterologist, or their registered nurse, administering potent anesthetics on the 15th floor of a general office building underscores my concern and the impending hazard. To reinforce the severity of this label change, the Connecticut state board of nursing went one step further by prohibiting non-anesthesia trained nurses to administer this anesthetic.

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It is my opinion that the healthcare and safety of our fellow citizens should not be compromised for pecuniary purposes, and that the current FDA warning label remain as stated. This will unequivocally ensure that patient safety is the number one priority for healthcare providers.

Your prominence as a physician, coupled with your interest and dedication to patient safety, positions you to be a tremendous advocate toward improving the quality of care in America.

Sincerely yours:

A handwritten signature in black ink, appearing to read 'Tom', with a stylized flourish extending from the end.

Thomas J. Herlihy
State Senator-8th District
Connecticut General Assembly

Cc: Parinda Jani